

**REMARKS**

This application is amended in a manner to place it in condition for allowance at the time of the next Official Action.

**Object to the Specification**

The Official Action objected to page 24 of the present specification for repeating "titanium dioxide" in Example 3, Composition 3. The second listing of titanium dioxide has been deleted for clarity.

**Status of the Claims**

Claims 19, 28, 29, 39, and 40 have been amended.

Claim 47 has been added.

The term "stabilized" in claims 19, 28, and 29 was replaced by the expression "hydroxypropylated or acetylated". This amendment is supported by page 8, lines 24-25 of the specification as filed.

Amended claim 19 now also specifies that the hydroxypropylated or acetylated starch is a legume starch. Accordingly, claim 23 has been cancelled.

In claim 39, the expression "including hard gelatin capsules" was deleted. This feature is now the subject of new claim 47.

In claim 40, the expression "at ambient temperature or under hot condition", which is also described on page 16, lines

1-6 of the specification, has been re-written as "at least at ambient temperature".

Claims 19-22 and 24-47 are currently pending.

**Claim Rejections-35 USC §112, 1<sup>st</sup> Paragraph**

Claims 19-28, 35 and 36 were rejected under 35 U.S.C. §112, first paragraph, for not complying with the written description requirement. This rejection is respectfully traversed for the reasons below.

These claims were rejected for reciting the term "stabilized". However, this rejection has been overcome by replacing the term "stabilized" by the definition given at page 8, lines 24-25 of the specification as filed, i.e. by the expression "hydroxypropylated or acetylated".

Therefore, the claims comply with the written description, and withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §112, 2nd Paragraph**

Claims 19-28, 35, 36, 39 and 40 were rejected under 35 U.S.C. §112, second paragraph, for being indefinite. This rejection is respectfully traversed for the reasons below.

These claims were rejected for reciting the terms "stabilized" in claim 19, "including hard gelatin capsules" in claim 39 and "hot conditions" in claim 40.

However, this rejection has been overcome by replacing the term "stabilized" by the expression "hydroxypropylated or acetylated" as discussed previously, re-writing the temperature range to "at least ambient temperature", and removing the "including hard gelatin capsules" in claim 39 (and adding it as new claim 47).

Therefore, the claims are definite, and withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §102**

Claims 19-24, 36-38 and 40 were rejected under 35 U.S.C. §102(b) as being anticipated by LYDZINSKI et al. U.S. 2003/0099692 (LYDZINSKI). This rejection is respectfully traversed for the reasons that follow.

LYDZINSKI describes a film forming composition comprising a modified starch (see [0005]). The starch may be corn, pea, potato, sweet potato, banana, barley, wheat, rice, sago, amaranth, tapioca, arrowroot, canna, sorghum, and waxy or high amylase varieties thereof (see lines 1-5 of [0009]).

In the list of starches given in LYDZINSKI, the only legume starch is pea starch. Moreover, LYDZINSKI lists a large variety of possible physical, chemical, and/or enzymatic modifications (see [0011] to [0013]).

The starches used in the examples of LYDZINSKI are modified high amylose or waxy corn starches and native tapioca

starch. Moreover, none of the compositions of Examples 1 and 2 comprising modified corn starches has an amylose content of between 25 and 40 % by dry weight with respect to the dry weight of starch present in the composition. In fact, the high amylose starch has an amylose content of 70% (see [0039]) and the waxy corn starches have an amylose content of at most 5 % (see [0040], [0042] - [0045], and [0009], which specifies that waxy starches have an amylopectin content of at least 95% and thus an amylose content of at most 5%).

There is furthermore no specific disclosure in LYDZINSKI of the use of legume starch and even less of composition having an amylose content of between 25 and 40 % by dry weight with respect to the dry weight of starch present in the composition and comprising at least one hydroxypropylated or acetylated legume starch.

As LYDZINSKI fails to teach each and every element of the claims, the presently claimed subject-matter is thus new in view of LYDZINSKI.

Therefore, withdrawal of the rejection is respectfully requested.

**Claim Rejections-35 USC §103**

Claims 25-27, 29, 30, 32-35, 41, 42, 43 were rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI. Claims 19, 28, 38, and 39 were rejected under U.S.C. § 103(a) as

being unpatentable over HAASMAA US 2002 0032254 (HAASMAA) in view of LEUSNER US 4,431,800 (LEUSNER) and further in view of KIM US 6,123,963(KIM). Finally, claims 31 and 44-46 were rejected under U.S.C. § 103(a) as being unpatentable over LYDZINSKI in view of FUERTES US 6,469,161 (FUERTES). These rejections are respectfully traversed for the reasons that follow.

The present invention relates to a

*"A film-forming starchy composition for the film coating of solid forms or for the preparation of films, wherein said composition exhibits an amylose content of between 25 and 45%, this percentage being expressed by dry weight of starch present in said composition, and wherein said composition comprises at least one hydroxypropylated or acetylated legume starch."*

See, e.g., independent claims 19, 29, 30 and 31.

**Claims 25-27, 29, 30, 32-35, and 41-43 are unobvious in view of LYDZINSKI:**

As set forth above in connection with the rejections under U.S.C. § 102(b), LYDZINSKI does neither teach nor suggest a film-forming composition as presently claimed.

Specifically, LYDZINSKI fails to teach the particular amylose content of the film-forming composition in combination with the use of a hydroxypropylated or acetylated legume starch as presently claimed.

Moreover, as shown in Example 1 of the present specification (see 16-21 of the specification as filed), the viscosities of compositions comprising waxy or amylose rich

hydroxypropylated starches are significantly higher than those of the compositions of the present invention. Due to these high viscosities waxy or amylose rich hydroxypropylated starch based compositions as those of LYDZINSKI cannot be applied to tablets by spraying under cold conditions.

Furthermore, compositions based on modified amylose rich corn starch as those of LYDZINSKI require high processing temperatures in order to prevent retrogradation of the starch and to allow acceptable spreading of the film. These high temperatures lead to significant evaporation of flavoring compounds when preparing flavor strips. The aromatic impact of the resulting flavor strips is thus significantly decreased and they do no longer have the desired freshening function (see example 2, page 22, lines 22-31 of the specification as filed).

Regarding the use of waxy starches, films formed from compositions containing waxy starches as those of LYDZINSKI do not exhibit the necessary cohesion. As a result they crack upon drying (see example 2, page 22, lines 33-37 of the application as filed).

There was thus a need for new starch based film-forming compositions that can be applied to tablets by spraying at cold temperatures and that are also suitable for the preparation of films that do not crack and that have a satisfactory aromatic impact.

LYDZINSKI is completely silent about the problems associated with the use of high amylose and waxy starches. LYDZINSKI can therefore not teach or suggest any solution to these problems and even less the claimed solution.

Very surprisingly and unexpectedly, the inventors have now found that a composition as presently claimed, i.e. having an amylose content of between 25 and 45% by dry weight of starch present in said composition, and comprising at least one hydroxypropylated or acetylated legume starch, overcomes the above-mentioned drawbacks of the compositions of LYDZINSKI (see Examples 1 and 2 of the application as filed).

Therefore, LYDZINSKI cannot render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

**Claims 19, 28, 38, and 39 are unobvious over HAASMAA in view of LEUSNER and further in view of KIM:**

None of HAASMA, LEUSNER, or KIM taken alone or in combination can remedy these shortcomings of LYDZINSKI for reference purposes for the reasons set out below.

HAASMAA describes a starch dispersion containing a modified starch ester dispersed in a liquid phase wherein the degree of substitution (DS) of the starch ester is greater than 1.5 (see claim 1). However, HAASMAA is completely silent about

suitable amylose contents. Moreover, regarding suitable starches for the dispersion, HAASMAA provides a quite exhaustive list of starch sources (see page 2, right column, lines 3-5), which includes barley, potato, wheat, oat, pea, corn, tapioca, sago, rice, or a similar rubber-bearing or rain plant. Hence, just as for LYDZINSKI, pea starch is just one possibility among a large variety of starch sources. The starches used in the Examples are always barley starches, which belong to the group of cereal starches. The skilled person therefore understands that the best starches for use in the invention of HAASMAA are barley starches, perhaps cereal starches.

Hence, HAASMAA completely fails to teach or suggest the particular amylose content of the film-forming composition in combination with the use of a hydroxypropylated or acetylated legume starch as presently claimed.

None of LEUSNER or KIM taken alone or in combination can remedy these shortcomings for the reasons set out below.

LEUSNER relates to a method for hydroxypropylating starch. In column 1, lines 23-24 it is mentioned that hydroxypropylation decreases the tendency towards retrogradation of the starches. LEUSNER is silent about starch sources.

Regarding the decreased tendency towards retrogradation of hydroxypropylated starches, the present inventors have shown that decreased retrogradation is often only obtained in combination with high processing temperatures. This however



creates other drawbacks, such as decreased flavor impact of the final film (see example 2, page 22, lines 22-31 of the specification as filed).

KIM teaches that conventional methods for coating tablets, granules, pellets, crystals, and capsules include coating in a fluidized bed and dip-coating (column 6, lines 58-65). However, KIM does not teach any film forming composition as presently claimed.

Consequently, LEUSNER and KIM cannot be used to remedy the shortcomings of HAASMAA. Therefore, HAASMAA in view of LEUSNER and further in view of KIM cannot render obvious the claimed invention, and withdrawal of the rejection is respectfully requested.

**Claims 31 and 44-46 are unobvious over LYDZINSKI in view of FUERTES:**

The teaching of LYDZINSKI is as set forth above, i.e. it fails to teach or suggest the particular amylose content of the film-forming composition in combination with the use of a hydroxypropylated or acetylated legume starch as presently claimed.

FUERTES, relates to a chemical fluidification process for a starchy material. However, FUERTES is completely silent about specific film-forming compositions, in particular

composition comprising hydroxypropylated or acetylated legume starch and having a certain amylose content.

As a consequence, FUERTES cannot be used to remedy the shortcomings of LYDZINSKI. Hence, the presently claimed subject-matter is indeed unobvious over LYDZINSKI in view of FUERTES and withdrawal of the rejection is respectfully requested.

**Conclusion**

In view of the amendment to the claims and the foregoing remarks, this application is in condition for allowance at the time of the next Official Action. Allowance and passage to issue on that basis is respectfully requested.

Should there be any matters that need to be resolved in the present application, the Examiner is respectfully requested to contact the undersigned at the telephone number listed below.

The Commissioner is hereby authorized in this, concurrent, and future submissions, to charge any deficiency or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

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